

**Amendments to the Drawings**

The attached sheet of drawings includes FIG. 3. This sheet, which includes FIG. 3, is to be added to the sheets of drawings as originally filed. FIG. 3 is identical to the diagram that was included at page 23 of the specification of the originally-filed application.

Attachment: Replacement Sheet

**Remarks**

**Introduction**

Claims 1-21 were pending. By way of this response, the specification, the drawings, and claims 1, 2, 3, 9, 12, 13, and 21 have been amended.

The specification has been amended by updating the "cross-reference to related applications" section, by updating the "drawings" section to include a brief description of FIG. 3, and by amending the paragraphs on page 23 to remove the figure that was included in the specification.

The drawings have been amended by adding FIG. 3 which is the diagram that was present on page 23 of the specification of the originally-filed application.

The claims have been amended to recite that the methods comprise examining first and second impressions, and comparing the first and second impressions to determine an effect of the botulinum toxin on a muscle. In addition, claims 2, 3, 12, and 13 have been amended to recite that the mean depth or length was of a plurality of wrinkles.

Support for the amendments to the specification, drawings, and the claims can be found in the application as originally filed, and care has been taken to avoid adding new matter. For example, support for the amendments to the specification can be found at page 23, line 3. Support for the amendments to the drawings can be found in the diagram at page 23 of the specification as originally filed. Support for the amendments to the claims can be found at least at page 19, lines 28-30; page 20, line 18; and page 20, lines 20-21.

In view of the amendments herein, claims 1-21 are currently pending, and applicant respectfully requests reconsideration of

the objections and rejections as they relate to the present specification and claims.

#### Information Disclosure Statement

The information disclosure statement (IDS) filed on 9/15/2003 was objected to and the information presented therein has not been considered.

Applicant is submitting a replacement IDS with the present Amendment. Applicant submits that the enclosed IDS complies with 37 CFR 1.98(a)(1), and applicant respectfully requests consideration of the information presented therein.

#### Objections

The Examiner has objected to the specification for including a figure on page 23 and for not reciting the patent number of the related parent application.

As indicated above, the specification has been amended to recite the patent number of the related parent application, to remove the figure from page 23, and by adding the figure from page 23 as FIG. 3 of the drawings, submitted herewith.

In view of the above, applicant submits that the specification is in proper form and requests that these objections be withdrawn.

#### Rejection Under 35 U.S.C. § 101

Claim 1-21 have been rejected under 35 U.S.C. § 101 as lacking utility. In particular, the Office Action states that the recitation of examining only one impression does not allow a comparison to be performed.

The claims have been amended as set forth above, and applicant traverses the rejections as they relate to the present claims.

Each of the present independent claims recites examining a first impression and examining a second impression, and comparing the first impression and the second impression.

In view of the above, applicant submits that the present claims satisfy the requirements of 35 U.S.C. § 101, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 3 and 13 have been rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the enablement requirement. In particular, the Office Action states that it is unclear how mean length of a wrinkle can be determined.

Claims 3 and 13 have been amended as set forth above, and applicant traverses the rejection as it relates to the present claims.

Claims 3 and 13 presently recite a mean length of a plurality of wrinkles.

In view of the above, applicant submits that the subject matter of the present claims, and claims 3 and 13 in particular, satisfy the requirements of 35 U.S.C. § 112, first paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-21 have been rejected under 35 U.S.C. § 112, second paragraph as being incomplete for not reciting examining both impressions. Claims 3 and 13 have been rejected under 35

U.S.C. § 112, second paragraph for not reciting more than one wrinkle such that "mean length" has meaning.

Applicant has amended the claims as set forth above, and applicant traverses the rejections as they relate to the present claims.

Each of the independent claims currently recites examining both the first and second impressions, and claims 3 and 13 currently recite a plurality of wrinkles.

In view of the above, applicant submits that the subject matter of the present claims satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

#### Double Patenting

Claims 1-21 have been rejected under the judicially created doctrine of obviousness-type double patenting over claim 8 of U.S. Patent No. 6,688,311.

Applicant will file a Terminal Disclaimer in the future upon the indication that the present claims are in condition for allowance.

#### Rejections Under 35 U.S.C. § 103

Claims 1-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ascher et al. (hereinafter Ascher) in view of Corcuff et al. (hereinafter Corcuff).

Applicant notes that Ascher is a French article and that the Examiner is relying upon the English summary and the figures.

Applicant has obtained an English translation of the article and has submitted the English translation in the

enclosed IDS. As discussed herein, applicant submits that Ascher, as evidenced by the English translation thereof, does not disclose, teach, or even suggest the method as described in the Office Action or as recited in the present claims.

Ascher discloses administration of botulinum toxin to treat glabellar wrinkles, crow's feet, and lower eyelid wrinkles. As described in the Material and Methods section on page 3 of the English translation, cutaneous impressions were obtained from the skin surface while the surface is at rest (page 3, third full paragraph). During polymerization of the silicone used to make the cutaneous impressions, the subject is resting and completely immobile (page 4, second full paragraph).

Corcuff discloses the use of silicone rubber impressions to study the effects of aging on skin wrinkles. Corcuff discloses the use of impressions made on the surface of patients' arms and the use of two floodlights to generate shadows behind the furrows (page 178, second full paragraph).

Applicant submits that the combination of Ascher and Corcuff does not disclose, teach, or suggest the present invention. For example, the combination of Ascher and Corcuff does not disclose, teach, or even suggest a method that comprises making a first impression while a muscle is at a first maximum voluntary contraction, and making a second impression while the muscle is at a second maximum voluntary contraction, as recited in the present claims.

As discussed above, Ascher specifically discloses that impressions were made on skin surfaces at rest (page 3, third full paragraph), and that the patients were resting and completely immobile during polymerization of the silicone used to make the impressions (page 4, second full paragraph). Thus, Ascher does not disclose, teach, or even suggest the method as

described in the Office Action or as recited in the present claims. For example, the method disclosed by Ascher specifically does not include at least two steps recited in the present claims (e.g., making the first impression while the muscle is at a first maximum voluntary contraction and making the second impression while the muscle is at a second maximum voluntary contraction).

Corcuff fails to provide the deficiencies apparent in Ascher. For example, Corcuff fails to disclose, teach, or even suggest a method for determining an effect of a botulinum toxin upon a muscle, let alone such a method which comprises making a first impression of a skin surface while a muscle is at a first maximum voluntary contraction, and making a second impression of a skin surface while the muscle is at a second maximum voluntary contraction, as recited in the present claims.

Since Ascher fails to disclose, teach, or even suggest all of the elements recited in the present claims, and since Corcuff fails to provide the deficiencies apparent in Ascher, applicant submits that the combination of Ascher and Corcuff does not disclose, teach, or suggest all of the elements recited in the present claims. Therefore, applicant submits that a *prima facie* case of obviousness has not been established, and the rejection under 35 U.S.C. § 103 cannot be properly maintained.

In addition, applicant submits that a person of ordinary skill in the art would not be motivated to combine the deficient teachings of Ascher and Corcuff, let alone do so and obtain the presently claimed invention.

For example, applicant submits that Ascher and Corcuff are directed to solving different and distinct problems. For example, Ascher is directed to analyzing some effects of botulinum toxin on certain types of facial wrinkles, and Corcuff

is directed to analyzing the effects of aging on different and distinct types of wrinkles (i.e., arm wrinkles). Not only is Corcuff directed to studying wrinkles that are different and distinct from the wrinkles studied by Ascher, Corcuff does not disclose, teach, or even suggest any pharmaceutical treatment of wrinkles, let alone, the use of impressions in studying the effects of pharmaceutical agents on wrinkles. The teachings of the references are so different and distinct that a person of ordinary skill in the art would not be motivated to combine the teachings or even consider such teachings since the references are directed to solving entirely different problems. Thus, applicant submits that a person of ordinary skill in the art given the teachings of Ascher would not be motivated to use or even combine the teachings of a reference, such as Corcuff, that are directed to completely different and distinct problems from the problem addressed by Ascher. This lack of a motivation is particularly clear since Corcuff does not disclose any use whatsoever of a pharmaceutical, such as a botulinum toxin, as recited in the present claims.

Furthermore, since Ascher specifically discloses that the impressions are made while the patient is at rest and is immobile, Ascher actually teaches away from the presently claimed methods which recite making impressions while a muscle is at a maximum voluntary contraction. "As a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)). Thus, since the references are directed to different problems, and since the primary reference teaches away from the present claims, applicant submits that a person of ordinary skill in the art would not be motivated to combine the deficient teachings of



the references, let alone do so and obtain the present invention.

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In view of the above, applicant submits that the present claims, that is claims 1-21, are unobvious from and patentable over Ascher and Corcuff, taken alone or in any combination, under 35 U.S.C. § 103.

Conclusion

In conclusion, applicant has shown that the present specification and drawings are in proper form, that the present claims satisfy the requirements of 35 U.S.C. §§ 101 and 112, and are unobvious from and patentable over the prior art under 35 U.S.C. § 103. As discussed herein, applicant will file a Terminal Disclaimer to overcome the obviousness-type double patenting rejection upon the indication that the present claims are otherwise in condition for allowance. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 12/27/05

Respectfully submitted,

  
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Attachments:  
One (1) sheet of drawings